Treatment Trials Activated August 2025

Research Base	Protocol #	Official Study Title	Indication/Disease	Planned Intervention	Abbreviated Eligibility Criteria Please refer to CTSU for the most recent version of the protocol.	Primary Objective	ClinicalTrials.gov NCT #	CTSU Activation Date	Approx. Target Accrual
ECOG-ACRIN	EAA241	A Randomized Phase II Trial Comparing Daratumumab-Bortezomib-Dexamethasone Versus Cyclophosphamide-Bortezomib-Dexamethasone in Newly Diagnosed Multiple Myeloma with Light Chain Cast Nephropathy (LCCN)	Newly diagnosed myeloma	Arm A: Cyclophosphamide-Bortezomib-Dexamethasone for 4 cycles Arm B: Daratumumab-Bortezomib-Dexamethasone for 4 cycles For both arms: Patients will be evaluated after 4 cycles of protocol therapy, at which time any and all further treatment – including transplant – is at the investigator's discretion	PVD: 6/25/2025 * Must be ≥ 18 years of age. * Must have an ECOG Performance Status 0-2. Patients with ECOG 3 are eligible if attributable to pathological fractures and/or cancer-related bone pain. * Must have MM and meet the following criteria: Bone marrow plasmacytosis with ≥ 10% plasma cells or sheets of plasma cells or biopsy-proven plasmacytoma **and** at least one myeloma-defining event (anemia, hypercalcemia, bone disease, renal dysfunction, clonal BMPCs ≥60%, Involved: uninvolved serum free light chain ratio ≥100, or > 1 focal lesions on MRI studies ≥5 mm) * Must have newly diagnosed (within the last 90 days) light chain cast nephropathy (LCCN) defined as patients with >1 g/dl proteinuria with <10% albuminuria, and/or an involved serum free light chain (FLC) concentration >150 mg/dL. * Must have new onset of renal failure (within the last 90 days) with one of the following criteria: an eGFR of <40 ml/min/1.73 m2 calculated with the Modification of Diet in Renal Disease (MDRD) formula, Serum creatinine >2 mg/dL, or on dialysis * May have received myeloma targeting therapy, including any of the following: cyclophosphamide, bortezomib and/or dexamethasone, as long as it was no more than one cycle AND the last dose administered was within 30 days prior to randomization. * Must not have been exposed to any prior or currently be on any anti-CD38 monoclonal antibodies * Must not have current or prior exposure to focal radiation therapy within 14 days prior to randomization with the exception of palliative radiotherapy for symptomatic management but not on measurable extramedullary plasmacytoma. See the protocol for organ, marrow, respiratory, cardiac, HIV, HBV, HCV parameters.	To determine whether incorporation of daratumumab-hyaluronidase into the treatment algorithm for newly diagnosed light chain cast nephropathy (LCCN) will improve efficacy measured by renal response rates (RRR) per International Myeloma Working Group (IMWG) renal response criteria over 4 cycles of treatment.	NCT07085728	8/11/2025	74
ECOG-ACRIN	EA2234	A Randomized Phase II/III Trial of Intraperitoneal Paclitaxel Plus Systemic Treatment vs Systemic Treatment Alone in Gastric Carcinomatosis - STOPGAP II	Gastric or Gastroesophageal junction (GEJ) adenocarcinoma	**Patients are randomized 1:1. All patients will be randomized in the operating room after the Peritoneal Cancer Index (PCI) score has been calculated by the surgeon.** **Arm A:** patients will receive any standard of care systemic therapy for 3 months. **Arm B:** patients will receive systemic therapy consisting of 5-FU, Leucovorin and IV Paclitaxel in addition to IP Paclitaxel for 3 months. **Both arms:** * Patients may also receive targeted therapies/immunotherapy. * Treatment will continue until progression, intolerance/unacceptable toxicity, or cytoreduction.	**PVD 7/14/2025** * Must be ≥ 18 years of age * Must have an ECOG 0-1 * Must have histologically or cytologically confirmed microsatellite stable (MSS) or Mismatch Repair (MMR) protein expression proficient primary gastric or gastroesophageal adenocarcinoma (Siewert 3) with synchronous cytology positive disease (cyt+) OR peritoneal carcinomatosis detected by imaging, laparoscopy or laparotomy. Patients with microsatellite instability-high (MSI-H/dMMR) Mismatch Repair deficient disease are not eligible. * Must have received a minimum of 3 months and a maximum of 6 months of first line systemic treatment * Must be registered to Step 0 within 4 weeks of the last dose of first line systemic therapy. * Must not have evidence of small or large bowel obstruction other than gastric outlet obstruction due to primary malignanc * Must not have evidence of solid organ metastases except for ovarian metastases *Must not have evidence of clinically significant radiologic peritoneal disease progression during first line systemic therapy * Must not have evidence of extensive retroperitoneal lymph node metastases not amenable to resection during gastrectomy * Must not have evidence of massive ascites on imaging or history of two therapeutic paracentesis with drainage of more than 1.0 liter of ascites each time in 30 days prior to Step 0 registration See the protocol for organ, marrow, cardiac, HIV, HBV, and HCV parameters	Phase II: to determine the progression free survival (PFS) from randomization. PFS is defined as the time from randomization to progression or death without documentation of progression. Phase III: to determine overall survival (OS) from randomization. OS is defined as time from randomization to the date of death (of any cause). The censored follow-up time for patients without death information is the date of last contact.	NCT07001748	8/19/2025	A max of 148 patients; 78 patients needed for the Phase II and 148 in total for the Phase III.

NRG	NRG-GU015	The Phase III Adaptive Radiation and Chemotherapy for Muscle Invasive Bladder Cancer Trial (ARCHER)	Urothelial carcinoma of the bladder	**Arm 1:** 4 weeks Radiosensitizing Chemotherapy + Hypofractionation (55 Gy/20 Fractions) **Arm 2:** 4 weeks Radiosensitizing Chemotherapy + SBRT (Ultra-hypofractionation) (32.5 Gy/ 5 Fractions) Types of chemo regimens: - Cisplatin - Gemcitabine - Mitomycin-C/5-Fluorouracil	**PVD: 7/16/2025** * Must have histologically proven, cT2-T3, N0M0 urothelial carcinoma of the bladder prior to randomization. Note: Patients with mixed urothelial carcinoma will be eligible for the trial, but the presence of small cell carcinoma will make a patient ineligible. * Must undergo a TURBT prior to randomization. Patients may have either completely or partially resected tumors as long as the treating urologist attempted maximal resection. * Must undergo radiological staging prior to randomization. * If any lymph nodes ≥ 1.0 cm in shortest cross-sectional diameter are noted on imaging (CT / MRI of abdomen and pelvis), then the patient must have had a biopsy of the enlarged lymph node showing no tumor involvement prior to randomization. * No diffuse CIS based on cystoscopy and biopsy * Must not have had urothelial carcinoma or histological variant at any site outside of the urinary bladder within 24 months prior to registration except Ta/T1/Carcinoma in-situ (CIS) of the upper urinary tract including renal pelvis and ureter if the patient had undergone complete nephroureterectomy. * Must be Age ≥ 18; * Must have Zubrod Performance Status of ≤ 2 * Must not have had prior pelvic radiation. * For patients who have completed neoadjuvant therapy, they are eligible if the preneoadjuvant therapy diagnosis (TURBT path) is within 180 days before randomization. See protocol for organ, marrow, and cardiac parameters	Demonstrate non-inferiority of ultra-hypofractionated (SBRT) compared to hypofractionated RT with a 10% non-inferiority margin (from 50% to 40%) in the rate of bladder-intact event-free survival (BI-EFS) at 3 years (corresponding to a hazard ratio	NCT07097142	8/14/2025	486